WRITTEN TESTIMONY

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HEARING ON
EPA's Integrated Risk Information System
Before the
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Good morning Chairman Broun, Ranking Member Edwards and other members of the Committee. My name is Paul Anastas. I am the Assistant Administrator for Research and Development (ORD) at the Environmental Protection Agency and the Agency's Science Advisor. It is a pleasure to be here with you this morning to discuss EPA's Integrated Risk Information System (IRIS).

Background and Description of IRIS Program

EPA recognizes the critical role we play in disseminating timely, high-quality and accessible human health risk information on environmental contaminants that may endanger the health of the American public. Central to this aspect of EPA's mission is its Integrated Risk Information System, commonly called the IRIS program, which provides health effects information on chemicals to which the public may be exposed from releases to air, water, and land and through the use and disposal of products. IRIS assessments provide a scientific foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws. While not regulations, IRIS assessments are critical to many Agency decisions. IRIS is also a resource for risk assessors and environmental and health

professionals in state and local governments and other countries. After becoming Administrator in early 2009, Administrator Jackson reviewed the IRIS program and asked the Office of Research and Development (ORD) in May 2009 to implement a new IRIS process that would revitalize the program and make it more responsive to the needs of the Agency. The aim of the new process was to ensure the highest level of scientific quality, integrity, transparency, and timeliness.

EPA's Actions to Implement the 2009 IRIS Process

EPA undertook several actions to implement the new IRIS process in 2009. EPA regularly solicits public comments on the IRIS agenda, and ORD works directly with program and regional offices to ensure that IRIS assessments meet their needs. To ensure that IRIS assessments are focused on the highest priority needs, EPA expanded the role of the program and regional offices in nominating and prioritizing chemicals for assessment.

EPA also has increased efforts to work with other agencies to share data and avoid duplication of effort. For example, ORD has a new Memoranda of Understanding with the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment in addition to an existing Memoranda of Understanding with the Agency for Toxic Substances and Disease Registry. These efforts help to increase efficiency and assessment output. The Agency is also working closely with its Science Advisory Board on how to bring to bear its expertise on an ongoing basis to focus on the quality, transparency, and scientific rigor of IRIS assessments and guide EPA's response to the NAS recommendations. We will add a peer consultation step to the early stages of major IRIS assessments to assure that the scientific community can provide input as we make critical design decisions for individual assessments. The Agency also created an IRIS logistics team to coordinate all administrative support to

improve efficiency and place increased emphasis on the scientific quality of assessments by allowing scientific staff to focus on the science. In addition, EPA developed the Health and Environmental Research Online database, referred to as HERO, which promotes transparency in risk assessments by capturing the literature used in EPA's health and environmental assessments and making the scientific studies used to develop assessments available to the public. The HERO database is web-based and accessible to everyone.

These actions, collectively, have led to improved results in the IRIS process. Specifically, EPA has completed 16 assessments since 2009, more than the number of assessments that were completed in the previous four years. EPA has reduced the IRIS backlog and is currently working on over 70 assessments. In 2010, EPA released nine assessments, seven of which were major assessments, for external peer review and public comment. Overall the new 2009 process resulted in greater involvement of EPA scientists and the public in the process.

In summary, there have been many improvements to the IRIS program since 2009 to provide high quality assessments in a timely fashion. Assessment development time was shortened to 23 months for most assessments, which will speed the availability of IRIS assessments for use by the risk assessment community and public. The IRIS program is now entirely managed by EPA and EPA strives to ensure that all of its science assessments undergo rigorous, open and independent external peer review and that multiple opportunities exist for public review and comment. Additionally, changes in IRIS assessments that occur during the interagency and public process are documented and explained, ensuring a transparent final product.

IRIS Process and the NAS Review

In April 2011, the NAS released its review report of EPA's draft IRIS risk assessment of formaldehyde and included comments and recommendations to improve the IRIS process. EPA welcomes those recommendations and will be addressing all of them in a phased-in fashion. We note that the NAS specifically focused their comments on the development of draft IRIS assessments and did not recommend changes to the steps that occur later in the process. Additionally, the NAS recognized that EPA's implementation of their suggested changes would require a multiyear process. A summary of the NAS overall recommendations and EPA's responses to them are described below.[1]

1. **NAS recommended that EPA rigorously edit documents to reduce the text volume and address redundancies and inconsistencies.**

   To respond to this recommendation, EPA is rigorously editing our assessment documents to substantially reduce the volume of text and address redundancies and inconsistencies; building on the existing IRIS guidelines and process to enhance the clarity and transparency of data evaluation and the presentation of findings and conclusions;

[1] Full text from p. 152 of the final published NAS report.

- To enhance the clarity of the document, the draft IRIS assessment needs rigorous editing to reduce the volume of text substantially and address redundancy and inconsistency. Long descriptions of particular studies, for example, should be replaced with informative evidence tables. When study details are appropriate, they could be provided in appendixes.
- Chapter 1 needs to be expanded to describe more fully the methods of the assessment, including a description of search strategies used to identify studies with the exclusion and inclusion criteria clearly articulated and a better description of the outcomes of the searches (a model for displaying the results of literature searches is provided later in this chapter) and clear descriptions of the weight-of evidence approaches used for the various non-cancer outcomes. The committee emphasizes that it is not recommending the addition of long descriptions of EPA guidelines to the introduction, but rather clear concise statements of criteria used to exclude, include, and advance studies for derivation of the RfCs and unit risk estimates.
- Standardized evidence tables for all health outcomes need to be developed. If there were appropriate tables, long text descriptions of studies could be moved to an appendix or deleted.
- All critical studies need to be thoroughly evaluated with standardized approaches that are clearly formulated and based on the type of research, for example, observational epidemiologic or animal bioassays. The findings of the reviews might be presented in tables to ensure transparency. The present chapter provides general guidance on approaches to reviewing the critical types of evidence.
- The rationales for the selection of the studies that are advanced for consideration in calculating the RfCs and unit risks need to be expanded. All candidate RfCs should be evaluated together with the aid of graphic displays that incorporate selected information on attributes relevant to the database.
- Strengthened, more integrative, and more transparent discussions of weight of evidence are needed. The discussions would benefit from more rigorous and systematic coverage of the various determinants of weight of evidence, such as consistency.

consolidating related discussions to eliminate redundancies; increasing the use of tables and figures to improve communication of information; and providing reference information on the IRIS website for all studies considered.

2. **NAS recommended that EPA include a fuller discussion of methods and develop concise statements of the criteria used to exclude, include and advance studies for hazard evaluation and derivation of toxicity values.**

   In response to this recommendation, EPA is providing a fuller discussion of the methods used in our assessments, along with concise statements of the criteria used to exclude, include, and focus on the highest quality studies for hazard assessment and for derivation of toxicity values.

3. **NAS recommended standardized evidence tables for all health outcomes.**

   EPA is working towards replacing text descriptions of the studies with standardized evidence tables that provide the methods and results of each study for all health outcomes; and including text that will accompany evidence tables to present the criteria used to include or exclude studies.

4. **NAS recommended that EPA provide a clearer articulation of the rationale and criteria for screening studies.**

   To accomplish this, EPA is enhancing our sequential approach for progressively focusing on the most pertinent information, including: searching the literature, identifying the pertinent studies, and evaluating study characteristics; evaluating the overall weight of evidence for each health outcome; identifying plausible approaches for developing toxicity values; selecting the most pertinent data and developing toxicity values for each health hazard; and portraying toxicity information graphically.

5. **NAS recommended that EPA use uniform approaches to thoroughly evaluate the strengths and weaknesses of critical studies, summarize findings in tables, and clearly articulate the rationale for the studies used to calculate toxicity values.**

   To respond to these two suggestions EPA is streamlining IRIS assessment documents and more fully document our approach for assembling and evaluating the range of scientific data. As the NAS report indicated, we have already made similar changes to how we present the scientific evidence on the criteria air pollutants in our Integrated Science Assessments, and we are confident we can make comparable improvements in how we present our analysis of health study findings for chemicals evaluated in the IRIS program. EPA is also implementing a more uniform approach to our evaluation of the strengths and weaknesses of critical studies to increase the clarity of the rationale for selecting the studies used to calculate toxicity values. Lastly, we are increasing the use of evidence tables that summarize the factual details of pertinent studies for each health hazard and developing standardized language to describe study strengths and limitations.

6. **NAS recommended that EPA provide descriptions to indicate various determinants of weight of evidence to promote understanding of what elements were emphasized in synthesizing the evidence.**

   In response, EPA is augmenting its current analysis of data to indicate which criteria were most influential in evaluating the weight of evidence.

Timeline for Responding to NAS Recommendations

EPA's overarching goal is to continually improve our IRIS assessments, recognizing that these improvements will have a greater impact on our new assessments as opposed to those already in the pipeline. It is important to note that the NAS report viewed the implementation of

their recommendations as a multi-year process. For example, the NAS stated 'it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach." To that end, EPA is doing the following:

- ***Assessments that have already been peer-reviewed or released for peer review***: We are revising these assessments to address peer review comments, especially those that call for increased transparency of study selection and evidence evaluation.
- ***Assessments currently under development but not yet released for peer review***: We are re-examining these assessments to ensure that the rationale for study selection and evidence evaluation is clear. These assessments will also be edited to reduce redundancy.
- ***New assessments that have not yet been started***: We will fully implement the NAS recommendations for new assessments, including a tighter document structure, evidence tables to summarize details from pertinent studies, greater transparency in study selection and evaluation criteria, and greater emphasis on clear analysis and synthesis.

The standards to which IRIS assessments are held, including the rigorous independent external peer review of every draft IRIS assessment, are among the best in the federal government and the scientific community. Over the coming months, the IRIS program will fully implement the NAS recommendations and continue to improve the IRIS process to reflect the highest standards of scientific integrity and credibility. Strengthening and streamlining the IRIS process is a continuing and ongoing priority for EPA. Thank you for the invitation to share my thoughts on this important topic. I will gladly answer any questions you have.